IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	) Examiner: M. Davis
Steven H. Hinrichs et al.	) Art Unit: 1642
Serial No. 09/519,665	) Response to Paper No: 4
Filed: March 6, 2000	)
For: "Methods and Compositions For Modulating Transcription Factor Activity"	)

Harry
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TRAVERSAL OF RESTRICTION REQUIREMENT

A restriction requirement under 35 U.S.C. §121 was set forth in the Official Action dated July 5, 2001 in the above-identified patent application. It is the Examiner's position that claims 1-55 in the present application are drawn to thirty-six (36) patentably distinct invention which are as follows:

Group I: Claims 1-5, 8, 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain and the transcriptional factor is B-ZIP;

Group II: Claims 1-4, 6, 8, and 17-22, drawn to a method

for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain and the transcriptional factor is a helix-loop-helix protein;

Group III: Claims 1-4, 7, 8 and 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain and the transcriptional factor is a zinc finger protein;

Group IV: Claims 1-4, 9-14 and 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain and the transcriptional factor is fusion protein EWS/ATF1;

Group V: Claims 1-4, 9-13, 15 and 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain and the transcriptional factor is fusion protein EWS/FLI;

Group VI: Claims 1-4, 9-13, 16 and 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing

said transcriptional factor to an inhibitory agent, which binds to a linker domain and the transcriptional factor is fusion protein PAX/FKHR;

Group VII: Claim 23, drawn to a method for screening modulators of B-ZIP transcription factor;

Group VIII: Claim 23, drawn to a method for screening modulators of a transcription factor which is a helix-loop-helix protein;

Group IX: Claim 23, drawn to a method for screening modulators of a transcription factor which is a zinc finger protein;

Group X: Claim 23, drawn to a method for screening modulators of a transcription factor which is EWS/ATF1;

Group XI: Claim 23, drawn to a method for screening modulators of a transcription factor which is EWS/FLI;

Group XII: Claim 23, drawn to a method for screening modulators of a transcription factor which is PAX/FKHR;

Group XIII: Claims 24-32, drawn to a method for treating an individual having transcriptional factor-mediated disease, comprising exposing a B-ZIP transcriptional factor to an inhibitory agent which binds to a linker domain of said transcriptional factor;

Group XIV: Claims 24-32, drawn to a method for treating an individual having transcriptional factor-mediated disease, comprising exposing a transcriptional factor which is a helix-loop-helix protein to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XV: Claims 24-32, drawn to a method for treating an individual having transcriptional factor-mediated disease, comprising exposing a transcriptional factor which is a zinc finger protein to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XVI: Claims 24-32, drawn to a method for treating an individual having transcriptional factor-mediated disease, comprising exposing a transcriptional factor which is fusion protein EWS/ATF1 to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XVII: Claims 24-32, drawn to a method for treating an individual having transcriptional factor-mediated disease, comprising exposing a transcriptional factor which is fusion protein EWS/FLI to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XVIII: Claims 24-32, drawn to a method for treating an individual having transcriptional factor-

mediated disease, comprising exposing a transcriptional factor which is fusion protein PAX/FKHR to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XIX: Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a B-ZIP transcriptional factor;

Group XX: Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a helix-loop-helix protein transcriptional factor;

Group XXI: Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a zinc finger protein transcriptional factor;

Group XXII: Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a fusion protein EWS/ATF1 transcriptional factor;

Group XXIII: Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a fusion protein EWS/FLI transcriptional factor;

Group XXIV: Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a fusion protein PAX/FKHR transcriptional factor;

Group XXV: Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a B-ZIP transcriptional factor to an inhibitory agent,

which binds to a linker domain of said transcriptional factor;

Group XXVI: Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a helix-loop-helix protein transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XXVII: Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a zinc finger protein transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XXVIII: Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a fusion protein EWS/ATF1 transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XXIX: Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a fusion protein EWS/FLI transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XXX: Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a fusion protein

PAX/FKHR transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XXXI: Claims 49-55, drawn to Claims 1-5, 8 and 17-22, drawn to a method for modulating transcriptional factor-mediated cellular proliferation, comprising exposing a B-ZIP transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XXXII: Claims 49-55, drawn to a method for modulating transcriptional factor-mediated cellular proliferation, comprising exposing a helix-loop-helix protein transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XXXIII: Claims 49-55, drawn to a method for modulating transcriptional factor-mediated cellular proliferation, comprising exposing a zinc finger protein transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XXXIV: Claims 49-55, drawn to a method for modulating transcriptional a factor-mediated cellular proliferation, comprising exposing fusion protein EWS/ATF1 transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor;

Group XXXV: Claims 49-55, drawn to a method for modulating

transcriptional factor-mediated cellular proliferation, comprising exposing a fusion protein EWS/FLI transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor; and

Group XXXVI: Claims 49-55, drawn to a method for modulating transcriptional factor-mediated cellular proliferation, comprising exposing a fusion protein PAX/FKHR transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor.

In addition, the Examiner indicates that upon the election of any of groups I-XXXVI, further election of either an antibody or subcomponent of an antibody, peptide mimetic or a non-peptide mimetic is required. Upon election of either groups I, VII, XIII, XIX, XXV or XXXI, further election of one member of the B-ZIP transcriptional factor family (e.g., CREB, ATF1, GCN4, AP-1) is required. Upon election of groups I-VI or XIII-XVIII, further election of neoplasia (Leukemia, lymphomas or sarcomas) or infectious disease is required.

Applicants respectfully traverse the restriction between the groups IV, XVI, XXII, XXVIII and XXIV inventions. A withdrawal or modification of the restriction requirement is clearly in order for the reasons set forth below.

According to the MPEP §803.01, there are two criteria for restriction between inventions which are alleged to be patentably distinct: 1) the inventions must be independent and distinct as claimed **and** 2) there must be a serious burden on the Examiner if the restriction is not required. Applicants respectfully that a proper search of the subject matter of claims 1-4, 9-14, and 17-22, drawn to methods of modulating EWS/ATF1 transcription factor-mediated gene expression,

claims 23-32, drawn to a method for screening for modulators of EWS/ATF1 transcription factor-mediated gene expression, claims 46-48 drawn to a method of modulating EWS/ATF1 transcription factor-mediated viral replication and claims 49-55 drawn to methods of modulating EWS/ATF1 transcription factor-mediated gene expression are necessarily coextensive. Indeed, the Examiner's description of the Group IV and Group XXXIV is **identical** and thus, these two groups of claims cannot be drawn to two distinct inventions. In light of the foregoing, a withdrawal or modification of the requirement is clearly in order.

In order to be fully responsive however, Applicants hereby elect the Group IV invention, namely claims 1-4, 9-14, and 17-22. Applicants elect the species of antibody or subcomponent of an antibody. Applicants further elect neoplasia and sarcoma in particular.

Applicants hereby reserve the right to file one or more continuation applications under 35 U.S.C.§120 on the subject matter of all claims ultimately withheld from consideration in the present application.

This invention represents an advance in the state of the art of transcription factor mediated gene regulation. Early and favorable action on this application is earnestly solicited.

Respectfully submitted,
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